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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,747	06/24/2003	Laura A. Bedzyk	CL1686USDI.V.	9974
23906	7590	03/29/2006	EXAMINER	
E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE WILMINGTON, DE 19805			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	
DATE MAILED: 03/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/602,747

Applicant(s)

BEDZYK ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 8, 9 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

This office action is in response to amendment filed 1/9/06. Claims 5-7, 10-13 and 17-28 have been cancelled. Claims 1, 2, 4, 8, 9 and 15 have been amended. Claims 1-4, 8, 9 and 14-16 are pending in the application.

#### *Response to Amendment*

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein and therefore, this action is final.

#### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8, 9 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action mailed 8/25/05 and restated below. The claim numbering has been amended to correct the typographical error in the office action mailed 8/25/05.**

The instant claims recite a method for the expression of a coding sequence using a promoter region of a *Bacillus subtilis* *yvaWXY* gene.

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The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants teach the identification of genes that are expressed in response to various stresses and environmental conditions using DNA microarray analysis. *Bacillus subtilis yvaWXY* was identified on the basis of its induction under oxygen depletion and under conditions of oxygen in stationary phase growth (see page 5, lines 8-12 and page 18, line 32). The nucleotide sequence of the *yvaWXY* is contained in SEQ ID NOs 8, 9 and 10 (see page 6-7). Applicants subsequently conclude that the promoter associated with these genes would function to drive expression of coding regions of interest under the conditions identified as inductive of the *yvaWXY* operon in the microarray. A sequence comparison demonstrates that SEQ ID NO:8 is the genomic sequence of *yvaW* exclusive of the promoter region. Applicants do not disclose the promoter region. Neither the prior art nor the specification teaches the structural requirements of the promoter region of *yvaWXY* required to mediate gene expression in the absence of oxygen or in the presence of oxygen until the cell reaches about T0 of the stationary phase. Therefore, applicants claim the promoter without any disclosure about its structure or structural requirements. The skilled artisan would not conclude that applicant was in possession of a chimeric gene comprising the recited promoter.

***Response to Argument***

Applicants traverse the claim rejections under 35 U.S.C. 12, first paragraph on pages 3-5 of the amendment filed 12/5/05. Applicants argue that as genome of the *Bacillus subtilis* genome and the coding region of *yvaV* (upstream of *yvaW*) and of *yvaW* were known, a skilled person will recognize that the promoter region will lie upstream of the *yvaW* coding region prior to the end of the *yvaV* coding region and would easily be able to discern the portion of the genome containing the promoter region in question.

Applicants' arguments filed 12/5/05 have been fully considered but they are not persuasive. Applicants' claims are drawn to a chimeric gene comprising the promoter region of a *Bacillus subtilis yvaWXY* gene. Applicants' claims are drawn to "the promoter region"; however, applicants do not define "a promoter region". The specification defines a promoter as a DNA sequence capable of controlling the expression of a coding sequence or functional RNA. However, it is not clear if a promoter region is the same thing or if it encompasses a broader or narrower scope than "a promoter". The specification does not provide the structural requirements of a promoter or a promoter region of a *Bacillus subtilis yvaWXY*. Applicants have argued that a skilled person would recognize that the region between *yvaV* and *yvaW*. However, applicants have not defined the promoter region that is responsible for directing expression in the absence of oxygen or in the presence of oxygen until the cell reaches about T0 of the stationary phase. An adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is the knowledge in the prior art and/or a description as to the availability of a

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representative number of species of claimed nucleic acid sequences. However, applicants have claimed the promoter region without providing a description of the components of the promoter. Therefore, the promoter region must be determined empirically in order to generate the promoter region as applicants claim the promoter without any disclosure about its structure. Without the structural requirements of the promoter, the skilled artisan would not conclude that applicant was in possession of the promoter region of a *Bacillus subtilis* yvaWXY gene.

### ***Conclusion***

Claims 1-4, 8, 9 and 14-16 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

March 15, 2006



**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**